FDA 510(k) Premarket Notification

**CLEARED**

# K232954 BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel

Mar 26, 2024
187 days to decision

K232954 · Product code: **QOF** · Microbiology
Source: https://www.510kdatabase.net/k232954/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Dual Track |
| Device classification | Multi-target Respiratory Specimen Nucleic Acid Test Including Sars-cov-2 And Other Microbial Agents (QOF) |
| Date received | Sep 21, 2023 |
| Decision date | Mar 26, 2024 |
| Days to decision | 187 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Biofire Diagnostics, LLC** |
| Location | Salt Lake City, UT, US |
| Contact | Kevin Bourzac |
| Website | http://www.biofiredx.com/ |
| 510(k) history | 28 submissions · 24 cleared · 2015-2025 |

Biofire Diagnostics, LLC specializes in microbiology diagnostic systems for syndromic infectious disease testing. The company, with a manufacturing facility in Salt Lake City, develops rapid molecular diagnostic platforms that detect viruses, bacteria, parasites, yeast, and antimicrobial resistance genes. The BIOFIRE® FILMARRAY® System and BIOFIRE® SPOTFIRE® System deliver results in approximately one hour. Biofire Diagnostics has received FDA 510(k) clearances from total submissions since its first clearance in 2015. The company maintains 100% focus on microbiology devic...

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **bioMerieux, Inc.** |
| Contact | Kevin Bourzac |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov